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| 10/532,809 | 04/26/2005 | Seiji Yamada | 123655 | 8895 |

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OLIFF & BERRIDGE, PLC
P.O. BOX 320850
ALEXANDRIA, VA 22320-4850

| EXAMINER | |
|---|---|
| DHAROD, KHUSHAL R | |
| ART UNIT | PAPER NUMBER |
| 4111 | |

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| 08/13/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/532,809 | YAMADA, SEIJI | |
| | Examiner | Art Unit | |
| | KHUSHAL DHAROD | 4111 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *26 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/26/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because numbers referred in text are not shown on the drawing, for example, Col.6, ¶ 0062 discusses element 54,examiner is unable to find element 54. Furthermore, Fig. 2 shows section exploded view of Fig 1. The section on Fig. 1 that is illustrated in Figure 2 should be marked. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### *Claim Objections*

2. Claims 9-12 are objected to because of the following informalities: The claim states male die being filled with polymerizable monomer. Examiner interprets it being female die. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11 -12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 11 states "synthetic resin softened at high temperature". Without a proper guidance in the specification to provide a proper context on the term "high temperature", it is unclear what operating temperature can one reasonably considers the temperature to be "high". Softening range of synthetic polymers can vary widely depending on the type of polymers. Does "high temperature" merely require a temperature operating where it softens a polymer in question?

6. Claim 12 states "synthetic resin being mated used in a high temperature state". This claim is indefinite for essentially the same reason as above. More important, this claim is indefinite, because it is unclear whether the "high temperature" recited in this claim is referring back to the "high temperature" in claim 11. For the purpose of examining this claim, it is assumed that it does.

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seden et al., (US 4955580) in view of Clutterbuck US 6444145).

a. With respect to claims 1, 3 and 5-6, Seden et al. teach a contact lens forming die comprising male and female dies (all elements refer to Fig. 4, and

8a,Shown below: note: The mold shown in the Figure 8a is similar to that shown in FIG. 4 and the same reference numerals are used for equivalent parts).

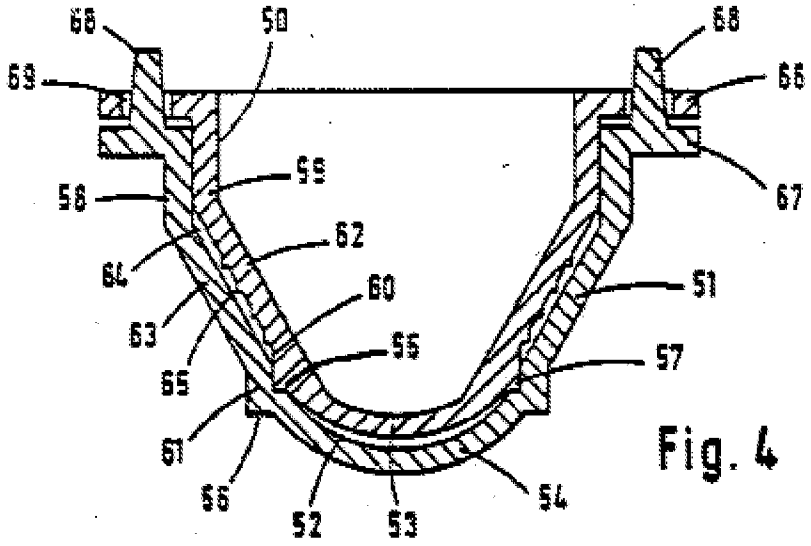


Fig. 4

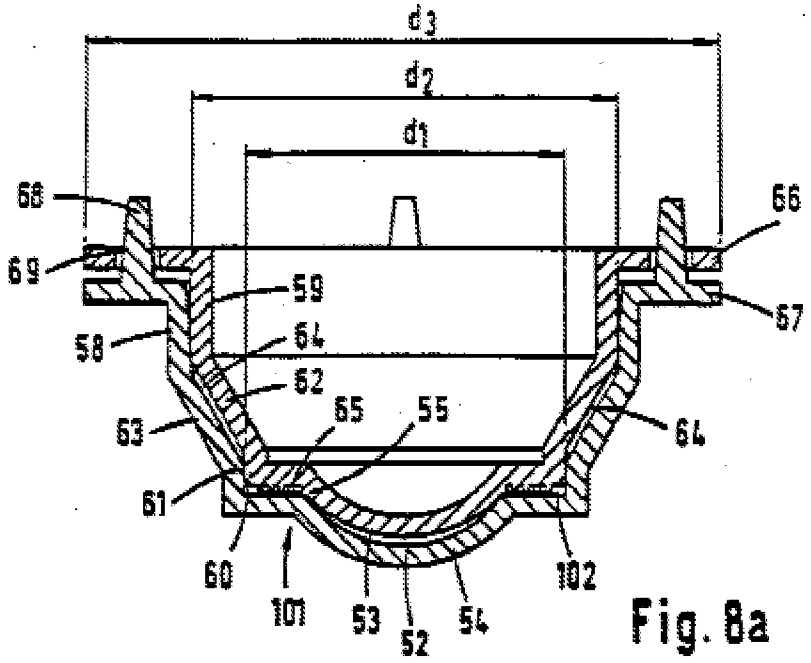


Fig. 8a

Mold halves 50 and 51constitute the male and female halves. The cavity is shown by element 52 which is adapted to be filled with polymerizable monomer (see abstract). The annular flat area formed abutting 55-56 of fig. 4 may range from 0.1 mm to 0.2mm and is orthogonal to the mating direction. Elements 58 and 59 form fitted tubular parts. Seden et al. teach an auxiliary cavity 65 (roughened forming snatch rings). Sedan et al.'s Fig. 4 elements 55 and 61 show abutting surfaces are orthogonal to the mating direction. Fig. 8a shows reservoir located between shoulders 55 and 56 but does not have abutting surfaces orthogonal to die mating surfaces. Sedan et al. fail to teach the combination of an abutting surface orthogonal to die mating direction with an auxiliary reservoir in one embodiment. However, it would have been obvious to the person having ordinary skill in the art to provide an auxiliary cavity with the abutting surfaces (55,56) which are orthogonal to the mating direction for an embodiment illustrated in Fig. 4 **or** to use an unroughened (i.e. flat) instead of roughened surface (65) for an embodiment shown in figure 8a thereby forming abutting surfaces in addition to the auxiliary cavity in Seden et al's invention, because Clutterbuck, drawn to a contact lens forming die of the type taught by Seden, teaches an embodiment in Fig. 1a, element 119 that provides an auxiliary cavity with abutting surfaces orthogonal to die mating direction to provide overflow channel for excess material and also provide formation of edge flat on the cast lens edge that lifts the front and back lens edge away from the wearer's conjunctiva smooth (col. 3 lines 18-27). Moreover, absent any showing unexpected benefit, a preference on whether to provide an auxiliary cavity to an embodiment illustrated in figure 4 similar to an embodiment shown in figure 8a **or** to

provide an unroughened (i.e. flat) abutting shoulders (55, 56) similar to an embodiment shown in figure 4 is taken to be well within the purview of choice in the art.

As for Claim 2, this claim would have been obvious in the art because the size of the auxiliary cavity will be designed to accommodate the excess monomer overflow. Therefore, one skilled in the art would design the capacity of the auxiliary cavity via routine experimentation.

As for Claim 4, this claim would have been obvious in the art because Clutterbuck's auxiliary cavity has a smooth surface devoid of bumps.

As for Claim 7, Sedan et al's tubular fitting portion is adjacent to the peripheral edge of the auxiliary cavity (see Fig. 4- elements 58 and 59).

As for Claim 8, Seden et al.'s reservoir is formed by elements 62 and 63 of Fig.4.

As for Claim 9, the discussion on the limitation in claim 1 is incorporated herein. As for the added process limitation, Seden et al.'s mold cavity 52 in Fig. 4 receives a measured volume of polymerizable monomer. (see Col. 5, lines 25-26). Furthermore, it states, "in the operation of the process of the present invention the lenses are cast within their mould cavities, opened after the appropriate polymerisation and curing time has been completed" see (col. 9, lines 3-5).

As for Claim 10, see Fig 4 of Seden et al which clearly shows the mating direction is vertical in order to form a contact lens.

As for Claim 11, Seden et al.'s mold is made from polyolefin (see abstract), where a polymerizable monomer is added into the mold cavity. Note: this claim does

not positively recite heating the molding dies at a "high temperature". Rather this claim merely indicates the characteristic (softened at a high temperature) of a polymeric die.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set in numbered paragraph 8 as applied to claim 11 above, and further in view of Keeley (US 4,931,228).

Since this is dependent on claim 11, it is assumed that at least one of the molding dies is softened state as it is at “a high temperature state”. The references set forth in numbered paragraph 8 above do not teach using at least one of the molding dies to be at a "high temperature", hence at a softened state (per claim 11). However, it would have been obvious in the art to use at least one of the modified molding dies of Seden et al to be at softened state, because Keeley, drawn to making contact lens, teaches operating at a temperature such that a molding die is at a softened state to greatly reduce "the stresses and strains the polymerization button is subjected to, to yield a stronger tear resistance end product." (col. 2 lines 48-59).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KHUSHAL DHAROD whose telephone number is (571)270-5520. The examiner can normally be reached on Monday-Thursday: 7:30AM -5:00PM(EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Sam C. Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KD/

/Sam Chuan C. Yao/
Supervisory Patent Examiner, Art Unit 4111